

### **Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

### **Listing of the Claims:**

Claims 1-61 (cancelled).

62. (previously presented): A recombinant nucleic acid molecule comprising:
- a nucleic acid sequence comprising SEQ ID NO:18; or
  - a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*; or
  - a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof.
63. (previously presented): The recombinant nucleic acid molecule of claim 62, wherein the nucleic acid molecule comprises a nucleic acid sequence comprising SEQ ID NO:18.
64. (previously presented): The recombinant nucleic acid molecule of claim 62, wherein the nucleic acid molecule comprises a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*.
65. (currently amended): The recombinant nucleic acid molecule of claim 64, wherein said protein corresponding to or being derived from atSRp30 protein from a plant other than

~~Arabidopsis thaliana further comprises atSRp30 activity, when overexpressed, to a truncated mRNA isoform of an atSRp34/SR1 protein.~~

66. (previously presented): The recombinant nucleic acid molecule of claim 62, wherein the nucleic acid molecule comprises a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof.
67. (previously presented): The recombinant nucleic acid molecule of claim 66, wherein the nucleic acid molecule binds to the nucleic acid molecule comprising SEQ ID NO:18, or is complementary thereto, under stringent conditions.
68. (previously presented): The recombinant nucleic acid molecule of claim 67, wherein the nucleic acid molecule encodes a splice protein active in plants.
69. (previously presented): The recombinant nucleic acid molecule of claim 62, wherein the recombinant nucleic acid molecule is comprised in an expression vector.
70. (previously presented): The recombinant nucleic acid molecule of claim 69, wherein the expression vector comprises a promoter.
71. (previously presented): The recombinant nucleic acid molecule of claim 70, wherein the promoter is an inducible promoter.
72. (previously presented): The recombinant nucleic acid molecule of claim 71, wherein the nucleic acid molecule is under the control of the inducible promoter.
73. (previously presented): The recombinant nucleic acid molecule of claim 62, wherein the recombinant nucleic acid molecule is comprised in a cell.
74. (previously presented): The recombinant nucleic acid molecule of claim 73, wherein the cell is a plant cell.

75. (previously presented): The recombinant nucleic acid molecule of claim 62, wherein the recombinant nucleic acid molecule is comprised in a plant.
76. (previously presented): A recombinant vector comprising a nucleic acid molecule including:  
a nucleic acid sequence comprising SEQ ID NO:18; or  
a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*; or  
a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof.
77. (previously presented): The recombinant vector of claim 76, wherein the vector is biologically functional.
78. (previously presented): The recombinant vector of claim 76, further comprising a promoter.
79. (previously presented): The recombinant vector of claim 78, wherein the promoter is an inducible promoter.
80. (previously presented): The recombinant vector of claim 79, wherein the nucleic acid molecule is under the control of the inducible promoter.
81. (previously presented): A transgenic plant or plant cell comprising a nucleic acid molecule including:  
a nucleic acid sequence comprising SEQ ID NO:18, or

a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*; or

a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof.

82. (previously presented): The transgenic plant or plant cell of claim 81, wherein the nucleic acid molecule is comprised in a vector.
83. (previously presented): The transgenic plant or plant cell of claim 82, wherein the vector is an expression vector.
84. (previously presented): The transgenic plant or plant cell of claim 83, wherein the expression vector comprises a promoter.
85. (previously presented): The transgenic plant or plant cell of claim 84, wherein the promoter is an inducible promoter.
86. (previously presented): The transgenic plant or plant cell of claim 85, wherein the nucleic acid molecule is under the control of the inducible promoter.
87. (previously presented): A method of changing the splicing properties of a plant or a plant cell comprising using a nucleic acid molecule that comprises:  
a nucleic acid sequence comprising SEQ ID NO:18; or  
a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to

222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*; or  
a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof.

88. (previously presented): The method of claim 87, wherein the nucleic acid molecule is comprised in a vector.
89. (previously presented): The method of claim 88, wherein the vector is an expression vector.
90. (previously presented): The method of claim 89, wherein the expression vector comprises a promoter.
91. (previously presented): The method of claim 90, wherein the promoter is an inducible promoter.
92. (previously presented): The method of claim 91, wherein the nucleic acid molecule is under the control of the inducible promoter.
93. (previously presented): A method of changing the development behavior of a plant or a plant cell comprising using a nucleic acid molecule that comprises:  
a nucleic acid sequence comprising SEQ ID NO:18; or  
a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*; or  
a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof.

94. (previously presented): The method of claim 93, wherein the nucleic acid molecule is comprised in a vector.
95. (previously presented): The method of claim 94, wherein said change of said development behavior is a retardation of flower formation.
96. (previously presented): The method of claim 95, wherein said flower formation is retarded by at least 15% relative to a wild-type of said plant.
97. (previously presented): The method of claim 96, wherein said flower formation is retarded by at least 25% relative to a wild-type of said plant.
98. (previously presented): The method of claim 93, wherein the nucleic acid molecule is comprised in a vector.
99. (previously presented): The method of claim 98, wherein the vector is an expression vector.
100. (previously presented): The method of claim 99, wherein the expression vector comprises a promoter.
101. (previously presented): The method of claim 100, wherein the promoter is an inducible promoter.
102. (previously presented): The method of claim 101, wherein the nucleic acid molecule is under the control of the inducible promoter.

**A Response to the Office Action Dated April 9, 2004:**

**A. Status of the Specification**

The Action objects to the specification for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. Applicants have amended the specification accordingly. No new matter has been added. Applicants request that this objection be withdrawn.

**B. Status of the Claims**

Claims 62-102 were pending at the time the Office Action dated April 9, 2004 was issued from the U.S. Patent and Trademark Office. Claim 65 has been amended. No new matter has been added by this amendment. Claims 62-102 are therefore currently pending.

**C. Submission of Foreign Priority Document**

Applicants are currently in the process of obtaining a certified copy of Austrian Application No. A 727/99 filed on April 23, 1999. Applicants will submit the certified copy to the U.S. Patent Office in due course.

**D. The Indefiniteness Rejection is Improper**

The Action rejects claims 62-102 for a variety of reasons under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants address each rejection in the following sub-sections.

**1. The term "atSRp30 Protein" is definite**

The Action contends that the phrase "'atSRp30' protein," as that term is used in claim 62, "is arbitrary and creates ambiguity in the claims." The Action asserts that the amino acid sequences disclosed in this specification could be designated by some other arbitrary means which would impair one's ability to determine the metes and bounds of the claim.

Applicants traverse. The phrase “atSRp30 protein” is definite and satisfies the statutory requirements of 35 U.S.C. § 112, second paragraph.

It is well settled that “[t]he test for definiteness under 35 U.S.C. § 112, second paragraph is whether those skilled in the art would understand what is claimed when read in light of the specification.” *See* MPEP § 2173.02 (citations and internal quotations omitted); *see also Miles Lab., Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993) (“If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, [section] 112 demands no more”).

The term “asSRp30 protein” is fully described and explained throughout the specification. *See, e.g.*, Applicants’ Specification, page 22, line 14, to page 27, line 8, lines 14-17. In non-limiting passages, the Specification characterizes the atSRp30 amino acid sequence and compares the sequence with other protein sequences. *Id.* at page 24, lines 7-14. In this regard, the specification states:

The derived protein sequences of atSRp30 and atSRp34/SR1 are very homologous (80.7% similarity and 67.1% identity) to each other, and both show very high similarity (75.3 and 77.8%, respectively) and identity (58.1 and 59.4%, respectively) to human SF2/ASF (Fig. 2). As atSRp30 and atSRp34/SR1 are less homologous to other animal or plant SR proteins identified to date, both proteins can be considered true orthologs of human SF2/ASF.

*Id.* It is clear from Applicants’ description that a person of ordinary skill in the art would understand the term “atSRp30 protein” by reading the specification. Because of this, 35 U.S.C. § 112, second paragraph, “demand no more” and the rejection should be withdrawn. *See Miles Lab.*, 997 F.2d at 875; *see also* MPEP § 2173 (noting that “[t]he primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent”).



Additionally, the Action's concerns that the term "atSRp30" "could be arbitrarily changed to designate a different amino acid sequence" is without basis. Applicants fully describe and explain "atSRp30" in their specification. *See, e.g.*, Applicants' Specification, page 22, line 14, to page 27, line 8, lines 14-17. It is well-settled that Applicants can be their own lexicographers. *See* MPEP § 2173.01 ("A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers"). Further, "a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought." MPEP § 2173.01.

The term "atSRp30 protein" is therefore definite when read in light of the specification. The rejection of claims 62-102 under 35 U.S.C. § 112, second paragraph, is improper and should be withdrawn.

**2. The phrase "being derived from atSRp30 protein" is definite**

The Action contends that the phrase "being derived from atSRp30 protein," as that term is used in claim 62, is indefinite. It is alleged that Applicants have not specified what encompasses "being derived from atSRp30" and that Applicants have not disclosed how one measures the derivation of a protein from another protein.

Applicants traverse. The phrase "being derived from atSRp30 protein" is definite and satisfies the statutory requirements of 35 U.S.C. § 112, second paragraph.

A person of ordinary skill in the art understands the meaning of the term "derived." This term is used in the specification in a number of instances. A person of ordinary skill in the art "would understand what is claimed when read in light of the specification." *See* MPEP § 2173.02. The present indefiniteness rejection is therefore improper. *Id.*

### 3. The phrase “atSRp30 activity” is definite

The Action contends that the phrase “atSRp30 activity,” as that term is used in claim 65 has not been defined. It is alleged by the Action that the specification “does not explicitly state the function or activity of the atSRp30 protein, *i.e.*, if the atSRp30 protein is involved in splicing mRNA, what sequence of mRNA does it bind to or splice.?”

Applicants traverse. The phrase “atSRp30 activity” is definite and satisfies the statutory requirements of 35 U.S.C. § 112, second paragraph.

The phrase “atSRp30 activity” is clear when read in light of the present specification and the present claims. For example, claim 65 depends from claim 64 which makes it clear that the “activity” referred to is “splicing factor activity in plants.” *See* present claim 64. The specification also explains that, in non-limiting embodiments, atSRp30 modulates alternative splicing of pre-mRNA *in vivo*. *See, e.g.*, Specification, page 35, line 20, to page 37, line 26. A person of ordinary skill in the art, therefore, would understand what is claimed when read in light of the specification. *See* MPAP § 2173.02.

The Action’s concerns of “what sequence of mRNA does [atSRp30 protein] bind to or splice” is without merit. It appears that the Action is equating the breadth of claim 65 with indefiniteness under 35 U.S.C. § 112, second paragraph. This is improper. *See* MPEP § 2173.04 (“Breadth of a claim is not to be equated with indefiniteness”). As noted in the above paragraph, the phrase “atSRp30 activity” is clear when read in light of the specification. *Id.* (“If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.”).

The term “atSRp30 activity” is therefore definite when read in light of the specification. The rejection of claims 62-102 under 35 U.S.C. § 112, second paragraph, is improper and should be withdrawn.

**4. The phrase “atSRp34/SR1 protein” is definite**

The Action contends that the phrase “atSRp34/SR1 protein,” as that term is used in claim 65, is arbitrary and creates ambiguity in the claims. It is alleged by the Action that the amino acid sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different amino acid sequence.

Applicants traverse. The phrase “atSRp34/SR1 protein” is definite and satisfies the statutory requirements of 35 U.S.C. § 112, second paragraph.

The present rejection appears to be analogous to the rejection addressed in sub-section D(1) above. The arguments made in that section are incorporated into this section by reference. For at least these reasons, the term “atSRp34/SR1 protein” is definite when read in light of the specification. The rejection of claim 65 under 35 U.S.C. § 112, second paragraph, is therefore improper and should be withdrawn.

**5. The phrase “to a truncated mRNA-isoform of an atSRp34/SR1 protein” is definite**

The Action contends that the phrase “to a truncated mRNA-isoform of an atSRp34/SR1 protein,” as that term is used in claim 65, is indefinite. It is alleged by the Action that it is not clear how atSRp30 protein expression leads to a truncated mRNA-isoform of an atSRp34/SR1 protein.”

Applicants traverse. The phrase “to a truncated mRNA-isoform of an atSRp34/SR1 protein” is definite and satisfies the statutory requirements of 35 U.S.C. § 112, second paragraph.

This phrase is clear when read in light of the present specification and the present claims and therefore the present indefiniteness rejection is improper. Applicants note, however, that “to a truncated mRNA-isoform of an atSRp34/SR1 protein” has been deleted from claim 65. The indefiniteness rejection is therefore rendered moot and should be withdrawn. Additionally, this limitation has been deleted from claim 65, and this claim is therefore broader in scope than what was originally presented, therefore it does not in any way, affect the scope of the claim or range of equivalents to which the elements in the claim are entitled.

**E. The Written Description Rejection is Improper**

**1. A Summary of the Rejection**

The Action rejects claims 62 and 64-102 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Action admits that the Application discloses SEQ ID NO:18 and SEQ ID NO:19 but contends that “Applicants do not reference SEQ ID NO:18 encoding SEQ ID NO:19 at all in the specification.” The Action, page 5. The Action also contends that the nucleic acid sequence disclosed in Figure 1A is 4073 base pairs long while SEQ ID NO:18 is 4044 base pairs long. The Action also alleges that the specification does not:

... identify essential regions of SEQ ID NO:19, essential regions of atSRp30, nor do Applicants describe any polynucleotide sequences that hybridize to SEQ ID NO:18 and encode a protein with the same function as SEQ ID NO:19 or sequences that are 90% sequence identical to amino acids 1 to 85 and 96 to 222 of SEQ ID NO:19 and have the same function as SEQ ID NO:19

The Action, page 5-6.

Applicants traverse. The presently claimed invention satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

## 2. The Standard for Establishing Written Description

The description in a specification “is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.” MPEP § 2163.04 (citing *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971)). The MPEP states:

The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a **preponderance of evidence** why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims.

*Id.*

The written description requirement is met if the “description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed.” MPEP 2163.02 (citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). Original claims constitute their own description. See *In re Koller*, 613 F.2d 819, 204 U.S.P.Q. 702 (C.C.P.A. 1980). The Federal Circuit has even stated that “an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.” *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336 (Fed. Cir. 2001).

## 3. The Specification Provides Written Description of Claims 62 and 64-102

The burden is on the Action to prove by a “preponderance of the evidence” that claims 62 and 64-102 lack written description in the specification. This has not been done. Rather, the Action has mischaracterized Applicants’ invention in attempting to support the present written description rejection. Applicants presently claim:

A recombinant nucleic acid molecule comprising:

[1] a nucleic acid sequence comprising SEQ ID NO:18; or

- [2] a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*; or
- [3] a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof.

Claim 62 (numberings [1], [2], and [3] are added to the claim for clarification of the arguments presented below). The present invention is also directed towards a corresponding recombinant vector (claim 76), a transgenic plant or plant cell (claim 81), or methods of changing the splicing properties or the development of a plant or plant cell (claims 87 and 93).

*i. The specification provides written description for element [1]*

Applicants' specification provides written description for the presently claimed invention. Element [1] is fully described in the specification. A complete listing of SEQ ID NO:18 can be found in the sequence listing. Figure 1A contains a mistake in the nucleotide sequence numbering: each nucleotide line contains 70 nucleotides. Therefore, the line next to 1416 in Figure 1 should be labeled 1486 and not 1496. This makes the total sequence length in Figure 1A 4044 and not 4054. This corresponds to the complete sequence listing number in SEQ ID NO:18.

*ii. The specification provides written description for element [2]*

Element [2] is also fully described in the specification. The nucleic acid and the amino acid sequences listed in Figure 1A correspond to SEQ ID NOS. 18 and 19, respectively. The specification indicates that the nucleic acid sequence encodes a protein "having splicing factor activity in plants." Specification, page 5 lines 23-27; *see also* page 8, lines 15-24; page 9, lines

7-13; page 11, lines 8-9; page 23, lines 25-26. The language of the specification is evidence that written description is present:

In a further aspect, the invention moreover relates to a system comprising a nucleic acid which encodes a protein according to any one of the claims, and a nucleic acid which encodes ... the protein corresponding to Fig. 1A from a plant other than *Arabidopsis thaliana* ... .

Specification, page 9, lines 7-13.

Fig. 1A shows a genomic sequence of atSRp30; promoter and intron sequences are indicated in lower-case, cDNA sequences in upper-case, and the TATA box in bold italics. The derived protein sequence is shown below the DNA in the one-letter code.

Specification, page 11, lines 5-9.

The sequence of GatSRp30 and the derived protein sequence are shown in Fig. 1A.

Specification, page 23, lines 25-26. The specification therefore provides written description for a “nucleic acid sequence encoding a protein ... comprising the amino acid sequence of SEQ ID NO:19.” *See* MPEP § 2163.02 (noting that the written description requirement is met if the “description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed”).

The specification also provides written description of “a nucleic acid sequence encoding a protein having splicing factor activity in plants ... comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID NO:19.” The amino acid sequence of SEQ ID NO:19 corresponds to Figure 1A. The specification states:

According to the invention, all proteins are preferred which comprise an amino acid sequence having at least 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the protein according to Fig. 1A of the appendix.

Specification, page 7, lines 14-18. This language is strong evidence showing that Applicants were “in possession of the invention” at the time the application was filed. *See* MPEP § 2163.02.

Further, this language provides a sufficient structural description of the invention. *See Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). SEQ ID NO:19 provides the full amino acid sequence. Applicants identify the positions of the amino acids that require 90% identity. The specification therefore provides written description for this portion of element [2] of the claimed invention.

The specification also provides written description of “a nucleic acid sequence encoding a protein having splicing factor activity in plants ... corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*.” The specification states:

In a further aspect, the invention moreover relates to a system comprising a nucleic acid which encodes a protein according to any one of the claims, and a nucleic acid which encodes ... the protein corresponding to Fig. 1A from a plant other than *Arabidopsis thaliana* ... .

Specification, page 9, lines 7-13. The specification notes that “Fig. 1A shows a genomic sequences of atSRp30. ... The derived protein sequence is shown below the DNA in the one-letter code.” Specification, page 11, lines 5-9. This language also provides a sufficient structural description of the invention. *See Regents of the University of California*, 119 F.3d at 1568. Written description for this element is therefore present in the specification. *See* MPEP § 2163.02.

***iii. The specification provides written description for element [3]***

Element [3], which states “a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof,” is described in Applicants’ specification. The specification states:

According to a further aspect, the present invention relates to nucleic acid molecules, which ... comprise a nucleic acid sequence which, under stringent



conditions, binds to the nucleic acid molecule according to Fig. 1A and encodes a splice protein active in plants or is complementary thereto.

Specification, page 8, lines 15-24. The nucleic acid sequence in Figure 1A corresponds to SEQ ID NO:18. This language provides written description for element [3].

Further, and despite the Action's contentions to the contrary, this language satisfies the standards set forth in *Regents of the University of California v. Eli Lilly*. The nucleic acid sequence of SEQ ID NO:18 defines the structural features for element [3]. Once a nucleic acid sequence is known, complementary sequences are known. For example, it is well known in the art that Adenine hybridizes with either Thymine or Uracil and Guanine hybridizes with Cytosine. Should the Action take a contrary position, Applicants request that the Action prepare and place an Affidavit in the file pursuant to 37 C.F.R. § 1.104(d)(2).

#### ***iv. Conclusion***

The Action has not shown by a "preponderance of the evidence" that claims 62 and 64-102 lack written description in the specification. Rather, as discussed above, the specification provides written description for these claims. The present written description rejection is improper and overcome for at least the reasons discussed in the above sub-sections.

The rejection of claims 62 and 64-102 under 35 U.S.C. § 112, first paragraph for lack of written description should therefore be withdrawn.

#### **F. The Enablement Rejection is Improper**

##### **1. A Summary of the Rejection**

The Action rejects claims 62-102 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Action contends that the subject matter of the claims was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Action presents several arguments to support its enablement rejection. Each argument is addressed by Applicants in the following subsection.

## 2. The Standard for Establishing Enablement

It is well-settled that “the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention.” MPEP § 2164.04. The standard for enablement has been stated by the Federal Circuit as:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation.

*United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988); *see also* MPEP § 2164.01. Enablement must bear only a **reasonable** relationship to the scope of the claims. *See In re Fisher*, 166 U.S.P.Q. 18, 24 (CCPA 1970). Moreover, the Federal Circuit has held that “[t]he enablement requirement is met if the description enables **any** mode of making and using the invention.” *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (emphasis added) (quoting *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)) (emphasis added). The MPEP confirms this by stating that “when a compound or composition claim is not limited by a recited use, **any enabled use** that would reasonably correlate with the entire scope of that claim **is sufficient** to preclude a rejection for nonenablement based on that use.” MPEP § 2164.01(c) (emphasis added). All that is required for enablement is **objective** enablement, not any particular level of efficacy. *In re Marzocchi*, 169 UPSQ 370 (CCPA 1971).

### 3. Claims 62-102 Are Enabled by the Specification

#### *i. Element [1] is enabled*

Element [1], which states “A recombinant nucleic acid molecule comprising: a nucleic acid sequence comprising SEQ ID NO:18,” is enabled by Applicants’ specification. The Action’s contends:

The specification fails to provide guidance for the explicit sequence Applicants are using to encode the atSRp30 protein. The sequence deposited at EMBL is 5164 bp’s long whereas the sequence in Figure 1A is 4073 bp’s long, while SEQ ID NO:18 is 4044 bp’s long. Applicants’ claims are drawn to SEQ ID NO:18 and SEQ ID NO:19 but Applicants do not reference these sequences at all in the specification.

The Action, page 9. The Action’s contention are unfounded.

As noted above, Figure 1A contains a mistake in the nucleotide sequence numbering. The sequence length in Figure 1A 4044 which corresponds to the complete sequence listing number in SEQ ID NO:18. Applicants also note that the sequence of atSRp30 submitted to the EMBL database contains an additional 1120 nucleotides upstream of SEQ ID NO:18. These additional nucleotides were omitted from Figure 1A because SEQ ID NO:18 contains the necessary nucleotide sequence that forms the basis of the data presented in this Application.

The specification discloses how to make SEQ ID NO:18. Applicants, in fact, fully describe SEQ ID NO:18. *See* Specification, page 11, lines 5-19. The specification provides examples of how to isolate and sequence a targeted DNA such as SEQ ID NO:18. *Id.* at page 16, line 11, to page 17, line 10. The Action appears to admit this. The Action, pages 8-9.

The specification also discloses how to use SEQ ID NO:18. In one non-limiting embodiment, the sequence was over-expressed in a transgenic plant. Specification, page 31, line 18, to page 34, line 4. The over-expression can result in phenotypic changes in plants. *Id.* at page 34, line 5, to page 35, line 19.

Based on the present specification and its corresponding data, a person of ordinary skill in the art could make and use the SEQ ID NO:18. Element [1] is therefore enabled by the specification.

*ii. Element [2] is enabled*

Element [2], which states “a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*” is enabled by Applicants’ specification. The Action’s contends otherwise by stating:

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that encode a protein exhibiting 90% sequence identity with amino acids 1 to 85 and 96 to 22 of SEQ ID NO:19, or sequences that hybridize to SEQ ID NO:18, or sequences that encode a protein that is derived from atSRp30 from a plant other than *Arabidopsis* will encode a protein with the same activity as a protein encoded by SEQ ID NO:18.

The Action, page 10.

The specification enables “a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19.” Applicants disclose the full amino acid sequence of SEQ ID. NO:19 and its corresponding nucleic acid sequence. Specification, Figure 1A. The specification provides non-limiting examples of how to make SEQ ID NO:19 from a nucleic acid. *See, e.g., Id.* at page 7, line 21, to page 22, line 12. In one non-limiting example, the application explains how a cDNA can be expressed in bacteria to obtain the corresponding protein. *Id.* The specification also provides data showing that the over expression of a nucleic acid encoding SEQ ID NO:19 can be used to affect plant development. *Id.* at page 31, line 18, to page 34, line 19. Because the specification

provides explanations and supporting data of how to make “a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19,” the specification therefore is enabling for this element. *See* MPEP § 2164.04.

The specification is also enabling for “a nucleic acid sequence encoding a protein having splicing factor activity in plants ... comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19.” The full amino acid sequence of SEQ ID. NO:19 and its corresponding nucleic acid sequence is disclosed. Specification, Figure 1A. A person of ordinary skill in the art would be able to determine a nucleic acid sequence that has at least 90% identity with a known amino acid sequence. This can be done, for example, by reference to a standard codon chart which does not require undue experimentation. Should the Action take a contrary position, Applicants request that an affidavit be prepared and submitted in the prosecution file pursuant to 37 C.F.R. § 1.104(d)(2). The specification also provides data showing that such nucleic acids can be used to affect plant development. *Id.* at page 31, line 18, to page 34, line 19. The specification therefore is enabling for this element. *See* MPEP § 2164.04.

The specification also enables “a nucleic acid sequence encoding a protein having splicing factor activity in plants ... corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*.” The specification notes that “the sequence of GatSRp30 and the derived protein sequence are shown in Fig. 1A.” Specification, page 23, lines 25-26. Such nucleic acids can be expressed in bacteria. *Id.* at page 7, line 21, to page 22, line 12. The specification also provides data showing that such nucleic acids can be used to affect

plant development. *Id.* at page 31, line 18, to page 34, line 19. The specification therefore is enabling for this element. *See* MPEP § 2164.04.

*iii. Element [3] is enabled*

Element [3], which states “a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof,” is enabled by Applicants’ specification. The Action’s contends that “[t]he state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe.” The Action, page 11. The Action, however, fails to note that nucleic acid hybridization technology is well-known and used throughout molecular biology.

Applicants teach how to make and use element [3] without undue experimentation. The specification, for example, discloses the full nucleic acid sequence of SEQ ID NO:18. Specification, Figure 1A. A person of ordinary skill in the art knows that Adenine hybridizes with either Thymine or Uracil and Guanine hybridizes with Cytosine. Based on this well-known fact, a person of ordinary skill would be able to identify a nucleic acid that binds to SEQ ID NO:18 without undue experimentation. *See In re Marzocchi*, 169 UPSQ 370 (CCPA 1971) (noting that all that is required for enablement is *objective* enablement, not any particular level of efficacy). The specification therefore is enabling for element [3]. *See* MPEP § 2164.04.

*iv. Additional issues raised by the Action are unfounded*

The Action makes general assertions regarding Applicants’ specification that are unfounded. In one instance, the Action states that “Applicants have not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicants’ broad claim language, that gives expected results when transformed into a plant.”

The Action, page 11. Applicants disagree and remind the Action that enablement must bear only a *reasonable* relationship to the scope of the claims. *See In re Fisher*, 166 U.S.P.Q. 18, 24 (CCPA 1970).

The specification includes specific data showing that the disclosed nucleic acid sequences, when transformed in a plant, affect that plant's development. *Id.* at page 31, line 18, to page 34, line 19. The specification, for example, notes that :

Overexpression of atSRp30 resulted in strong phenotypes with pleiotropic changes both in morphology and development of the transgenic plants. No significant differences were observed between plants transformed with pG30 and pC30 constructs, although the levels of atSRp30 protein were different (Fig. 6C, cf. lane 2 and lanes 3-7). The observations were reproducible in T<sub>2</sub> and subsequent generations of independent transgenic lines, and cosegregated with antibiotic resistance. In transgenic plants, the transition from vegetative to flowering stage was delayed greatly under short day conditions.

*Id.* at page 34, lines 6-16. This and other data in the specification provide a reasonable relationship to the scope of the present claims.

Applicants' specification is enabling for the entire scope of the presently claimed invention for at least the reasons discussed in the above sub-sections. The rejection of claims 62-102 under 35 U.S.C. § 112, first paragraph, for lack of enablement should therefore be withdrawn.

#### **G. The Anticipation Rejections are Improper**

The Action rejects claims 62-90, and 93-102 under 35 U.S.C. § 102(b) as being anticipated by Meyerowitz *et al.* (as to claims 62, 64-67, 69-86, and 93-102), Lazar (as to claims 62, 66-68, and 76-77), and Lopato *et al.* (as to claims 62-70, 73-78, 81-84, 87-90, and 93-100). A summary of each rejection and corresponding arguments are provided in the following sub-sections.

## **1. The Standard for Establishing Anticipation**

Anticipation requires that each and every element of the claimed invention be described, either expressly or inherently, in a single prior art reference. *See* MPEP § 2131 (citing *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)). It is well settled that the burden of establishing a *prima facie* case of anticipation resides with the Examiner and only if that burden is met, does the burden of going forward shift to the applicant. *See In re Sun*, 31 U.S.P.Q.2d 1451 (Fed. Cir. 1993).

## **2. Meyerowitz *et al.* Does Not Anticipate Claims 62, 64-67, 69-86, and 93-102**

The Action contends that claims 62, 64-67, 69-86, and 93-102 are anticipated by Meyerowitz *et al.* It is alleged by the Action that this reference discloses a tobacco plant transformed with a *Brassica napus* nucleic acid sequence operably linked to the 35S promoter. The Action further asserts that the transgenic tobacco plant produces flowers with retarded development comprising capeloid organs in the first and fourth whorls and staminoid in the second and third whorls. From this, the Action concludes that Meyerowitz *et al.* teaches every element of the claims listed above.

Applicants traverse. Meyerowitz *et al.* does not teach or suggest every element of claims 62, 64-67, 69-86, and 93-102.

The burden is on the Action to present a *prima facie* case of anticipation. *See In re Sun*, 31 U.S.P.Q.2d 1451 (Fed. Cir. 1993). The Action has not met this burden because it has failed to identify where Meyerowitz *et al.* teaches the elements claimed in the present invention. For example, claim 62 recites, in part: “a nucleic acid sequence comprising SEQ ID NO:18.” Where in Meyerowitz *et al.* is such a teaching present? It is the Action’s burden to identify these elements in a cited reference—not Applicants. In fact, it appears that SEQ ID NO:18 is not taught by the cited reference. SEQ ID NO:18 is 4044 nucleic acids long. The longest nucleic



acid sequence disclosed in Meyerowitz *et al.* appears to be only 1457 base pairs long. *See* Meyerowitz *et al.*, col. 19, line 16.

Claim 62 also recites “a nucleic acid sequence encoding a protein having splicing factor activity in plants, said protein comprising the amino acid sequence of SEQ ID. NO:19, or comprising more than 90% identity with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19, or corresponding to or being derived from atSRp30 protein from a plant other than *Arabidopsis thaliana*.” Where is this element disclosed in Meyerowitz? In fact, it appears that SEQ ID NO:19 is not disclosed in Meyerowitz *et al.* Additionally it appears that Meyerowitz *et al.* fails to mention or suggest the atSRp30 protein.

Claim 62 also recites “a nucleic acid sequence which binds to a nucleic acid molecule comprising SEQ ID NO:18 or its complement thereof.” Where is this element disclosed in Meyerowitz *et al.*? Again, it is the Action’s burden to identify the relevant teaching of a cited reference—a burden the Action has not met. Meyerowitz *et al.* does not appear to teach a nucleic acid sequence comprising 4044 nucleic acids (see SEQ ID NO:18)—much less a nucleic acid sequence which binds to SEQ ID NO:18.

Because Meyerowitz *et al.* does not appear to teach each and every element of the present invention, the present anticipation rejection cannot be maintained. Applicants request that the rejection of claims 62, 64-67, 69-86, and 93-102 as being anticipated by Meyerowitz *et al.* be withdrawn.

### **3. Lazar Does Not Anticipate Claims 62, 66-68, and 76-77**

The Action contends that claims 62, 66-68, and 76-77 are anticipated by Lazar. It is alleged that this reference discloses a nucleic acid sequence that exhibits 63% identity to a nucleic acid sequence encoding amino acids 1 to 85 and 96 to 222 of SEQ ID NO:19. The

Action further states that the Lazar sequence would bind to SEQ ID NO:18 under stringent conditions.

Applicants traverse. Lazar does not teach or suggest every element of claims 62, 66-68, and 76-77.

According to the Action, the Lazar nucleic acid sequence “exhibits **63% identity** (see enclosed sequence search result) to a nucleic acid sequence encoding amino acids 1 to 85 and 96 to 222 of SEQ ID NO:19.” The Action, page 14 (emphasis added). It appears that Lazar does not teach “more than 90% identity.”

By contrast, Applicants’ presently claim, in part, “a nucleic acid sequence ... comprising **more than 90% identity** with the sequence of the amino acids 1 to 85 and 96 to 222 of the amino acid sequence of SEQ ID. NO:19.” Claim 62 (emphasis added). Because Lazar does not appear to teach “more than 90% identity,” it does not anticipate the presently claimed invention.

Applicants request that the rejection of claims 62, 66-68, and 76-77 as being anticipated by Lazar be withdrawn.

**4. Lopato *et al.* Does Not Anticipate Claims 62-70, 73-78, 81-84, 87-90, and 93-100**

The Action contends that claims 62-70, 73-78, 81-84, 87-90, and 93-100 are anticipated by Lopato *et al.* This reference is not prior art to the presently claimed invention—much less 102(b) prior art.

The Lopato *et al.* reference was published in the April 15<sup>th</sup>, 1999 issue of Genes and Development (Vol. 13 Issue 8). Attached as Appendix A is a copy of a letter from the production editor of Genes and Development that shows that the Lopato *et al.* reference was actually released for mailing to the public on April 23<sup>rd</sup>, 1999. Therefore, the actual publication date for this reference is April 23<sup>rd</sup>, 1999.

Applicants presently claim priority to April 23<sup>rd</sup>, 1999 *via* Austrian Application No. A 727/99. Applicants are currently in the process of obtaining a certified copy of this reference and will submit it in due course. The Application's priority date therefore removes Lopato *et al.* as prior art. *See* 35 U.S.C. § 102(a) and (b).

Applicants request that the rejection of claims 62-70, 73-78, 81-84, 87-90, and 93-100 as being anticipated by Lazar be withdrawn.

#### **H. Conclusion**

Applicants believe that the present document is a full and complete response to the Office Action dated April 9, 2004. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested.

**A Petition for a One-Month Extension of Time:**

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of one month to and including August 9, 2004, in which to respond to the Office Action dated April 9, 2004. Pursuant to 37 C.F.R. § 1.17, a check in the amount of \$110.00 is enclosed, which is the process fee for a one-month extension of time for a large entity status. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/SONN:013US.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3035 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: August 9, 2004